

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0236838	(X3) Date Survey Completed 02/14/2024
Name of Provider or Supplier Manchin Clinic	Street Address, City, State 100 Main Street, Farmington, WV	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A routine recertification survey was conducted at Manchin Clinic on February 14, 2024, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. Specific deficiencies cited are explained below.
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to attain satisfactory scores for the chemistry analyte #0255 ALT in the 2nd proficiency testing (PT) event of 2023 and the chemistry analytes #0305 total bilirubin and #0345 total calcium in the 3rd proficiency testing (PT) event of 2023. Findings: 1. Review of CASPER 155D report identified the following unsatisfactory analyte score in the 2023 2nd PT event: #0255 ALT 20% 2. Review of CASPER 155D report identified the following unsatisfactory analyte scores in the 2023 3rd PT event: #0305 total bilirubin 20% #0345 total calcium 0% 3. Review of American Proficiency Institute (API) records confirmed the unsatisfactory scores for the analytes in the 2nd and 3rd PT event of 2023. 4. An exit interview with the technical consultant and testing personnel, 2/14/24 at 3:00 PM, confirmed the findings.</p>
D2098	<p>ENDOCRINOLOGY CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to attain a satisfactory score for the endocrinology analyte #0585 TSH in the 2nd proficiency testing (PT) event of 2023. Findings: 1. Review of CASPER 155D report identified the following unsatisfactory analyte score in the 2023 2nd PT event: #0585 TSH 40% 2. Review of American Proficiency Institute (API) PT records confirmed the unsatisfactory score of 40% for analyte #0585 TSH in the 2nd event of 2023. 3. An exit interview with the technical consultant and testing personnel, 2/14/24 at 3:00 PM, confirmed the findings.

D5425

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(3)

The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

This STANDARD is not met as evidenced by:
Based on review of written policies and procedures (P&P), quality control (QC) records, lack of documentation, and interview the laboratory failed to follow the established process for the verification of parameters for new lots of assayed quality control material in Chemistry and Hematology. Findings: 1. Review of P&P identified a Quality Control and Assessment Procedure for a Change in Lot stating for assayed controls each level is evaluated at least 5 times, results are compared to the product insert established ranges, filed, and retained. 2. Review of QC records (1/25/23 thru 12/18/23) for the Act Diff 2 revealed no documentation for the validation of 6 of 6 new lots of QC material. 3. Review of QC records (5/2/23 thru 12/30/23) for the Vitros XT 3400 revealed no documentation for the validation of 2 of 2 new lots of QC material. 4. During an interview 2/14/24 at 9:30 AM, the laboratory testing personnel (TP1) confirmed that no validation for new lots of QC occurred. 5. An exit interview with the technical consultant and TP1, 2/14/24 at 3:00 PM, confirmed the findings.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and interview the laboratory director failed to ensure the laboratory was enrolled in an approved proficiency testing program in the specialty of chemistry for the first event of 2023. Findings: 1. Review of CASPER 155D report and 2023 American Proficiency Institute PT records revealed no enrollment for the analytes in Chemistry for the 1st event of 2023. 2. No documentation of alternative assessment for the chemistry analytes could be located.

3. An interview with the testing personnel, 2/14/24 at 11:15 AM, confirmed the lack of enrollment and evaluation for the chemistry analytes. 4. An exit interview with the technical consultant and testing personnel, 2/14/24 at 3:00 PM, confirmed the findings.